UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,698	01/22/2002	David Moore Glover	CCI-017US	9996

7590 04/06/2005

EXAMINER
FETTEROLF, BRANDON J

ART UNIT	PAPER NUMBER
1642	

Giulio A DeConti Jr
Lahive & Cockfield
28 State Street
Boston, MA 02109

DATE MAILED: 04/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,698	GLOVER ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 15-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 15-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

L

DETAILED ACTION

The Amendment filed on 1/28/2005 in response to the previous Non-Final Office Action (09/29/2004) is acknowledged and has been entered.

Claims 1-3 and 15-21 are currently pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections Maintained:

Claims 1-3 **remain** rejected, 15-16 and **new claims 17-21** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record in the prior Office Action (10/05/2004, pages 3-6) and for the reasons set forth below.

In reference to the previous action (page 3-5) which held that the specification, "only reasonably conveys one species of Asp polypeptides (SEQ ID NO: 1) and therefore, is not commensurate with the full scope of any/all fragments thereof of having the amino acid sequence of SEQ ID NO: 1, Applicants contend that "the claims and specification provide sufficient written description for the fragments of Asp polypeptides." In particular, Applicants assert that the claims and specification characterize fragments of Asp as being capable of forming and/or maintaining MTOC's, describes particular regions of the Asp polypeptide (SEQ ID NO: 1), including for example, $p34^{cdc2}$ consensus phosphorylation sites, MAP kinase consensus phosphorylation sites, MPM2 epitope phosphorylation sites, putative binding sites and IQ motifs. Applicants further argue that the specification provides assays to determine whether a particular fragment possesses this functional property of forming and/or maintaining MTOC's. These arguments have been considered but are not found persuasive.

First, the previous rejection was based on the technical reasoning that necessarily flowed from the claims to the specification- i.e., whether the specification provided an adequate written

description for any and/or all Asp polypeptide fragments having the amino acid sequence shown in SEQ ID NO: 1. For example, the claims are drawn to an Asp polypeptide having the amino acid sequence shown in SEQ ID NO: 1, or a fragment thereof capable of forming and/or maintaining MTOCs. Therefore, the transitional phrase "having" in the claims permits the inclusion of other moieties extending from either the N terminal or C terminal region of the fragment. In addition, the transitional phrase "having" in relation to the fragment permits sequence, i.e. fragments, outside of the amino acid sequence of SEQ ID NO: 1. However, Applicants have not provided evidence to the contrary that they were in possession of the claimed genus of Asp peptide fragments having an amino acid sequence shown in SEQ ID NO: 1. For example, while Applicants allege that an Asp fragment as being capable of forming and/or maintaining MTOCs or comprises particular regions of the Asp polypeptide (SEQ ID NO: 1), applicants fail to mention the structural features which are common to the members of the genus. Secondly, Applicants arguments that the specification provides an assay to determining whether a particular fragment possesses the functional property of forming and/or maintaining MTOC's is not pertinent because the specification only shows the amino acid sequence of SEQ ID NO: 1. Therefore, one of skill in the art would not be apprised of what other amino acids could be hanging off of the Asp polypeptide. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

Although new claims 17-20 further limit an Asp protein fragment having an amino acid sequence shown in SEQ ID NO: 1, the transitional phrase "having" permits the inclusion of other moieties extending from either the N terminal or C terminal region of the fragment or a fragment which does not consist of the amino acid sequence recited in SEQ ID NO: 1. Thus, one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 21 recites, "wherein the polypeptide has between about 1 to about 30 substitutions, wherein the Asp polypeptide has microtubule organizing centre integrity." Thus claim 21 is drawn to a genus of Asp polypeptides which are not described in the specification. The specification only provides an Asp polypeptide consisting of the amino acid sequence of SEQ ID NO: 1. Thus, one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-3 **remain** rejected and claims 15-16 and **new claims 17-21** are under 35 U.S.C.

112, first paragraph, because the specification, while being enabling for identifying a substance capable of disrupting microtubule organizing centre (MTOC) integrity by contacting an Asp polypeptide consisting of the amino acid sequence of SEQ ID NO: 1, does not reasonably provide enablement for identifying a substance capable of disrupting microtubule organizing centre (MTOC) integrity by contacting any and/or all fragments thereof having an amino acid sequence of SEQ ID NO: 1 for the reasons of record (Pages 5-7) in the Action mailed 9-24-2004 and for the reasons set forth below.

In reference to the previous action which held that the specification does not provide enablement for identifying a substance capable of disruption microtubule organizing centre (MTOC) integrity by contacting any and/or all fragments thereof having an amino acid sequence of SEQ ID NO: 1 , Applicants contend that "one skilled in the art would be able to identify the functional properties of Asp polypeptide fragments through either standard assays known in the art or through those provided in the specification." Applicants further assert that the specification provides Asp binding assays, MTOC nucleation activity assay and whole cell assays to allow for the production and identification of ASP polyeptide fragments that possess the MTOC integrity functional property. Moreover, Applicants argue that the specification describes particular regions of an Asp polypeptide, including for example, p34cdc2 consensus phosphorylation sites, MAP kinase consensus phosphorylation sites, MPM2 epitope phosphorylation sites, putative biding sites and IQ motifs that may confer the necessary functional properties of the polypeptide to the fragments. These arguments have been carefully considered but are not found persuasive.

First, the previous rejection was based on an analysis of whether the disclosure, when filed, supported whether any and/or all fragments having an amino acid sequence of SEQ ID NO: 1 can be used for identifying a substance capable of disrupting MTOC integrity, as long as the fragments are capable of forming and/or maintaining MTOC in the absence of the substance as to enable one skilled in the pertinent art to make and use the claimed invention. Applicants have not provided evidence that any/and or all fragments of Asp protein are capable of acting this way. For example, while Applicants allege that the specification describes particular regions that may (emphasis added) confer the necessary functional properties of the polypeptide to the fragment and further provides assays for analyzing the function properties of the fragments, Applicants fail to provide examples wherein a Asp polypeptide fragment was capable of functioning as it is claimed. The specification,

as described in the previous office action on page 6 bridging page 7, teaches that peptides (fragments) consisting essentially of 5 to 35 amino acids comprising an amino acid sequence selected from residues x-y (generic term) of SEQ ID NO: 1 are capable of disrupting MTOC integrity. Thus, as stated previously, the teachings do not clearly indicate that any and/ or all fragments of an Asp polypeptide (SEQ ID NO: 1) are capable of functioning this way and would require undue experimentation by one skilled in the art to practice the claimed invention. In addition, the transitional phrase "having" permits the inclusion of other moieties extending from either the N terminal or C terminal region of the fragment. In addition, the transitional phrase "having" in relation to the fragment permits sequence, i.e. fragments, outside of the amino acid sequence of SEQ ID NO: 1. Thus, those skilled in the art recognize that protein chemistry is probably one of the most unpredictable areas of biotechnology for the reasons of record (page 7).

Although new claims 17-20 further limit an Asp protein fragment having an amino acid sequence shown in SEQ ID NO: 1, the transitional phrase "having" permits the inclusion of other moieties extending from either the N terminal or C terminal region of the fragment. Thus, it would require undue experimentation for one skilled in the art to practice the invention as claimed for the reasons stated above and in the previous office action. Thus claim 21 is drawn to a genus of Asp polypeptides which are not described in the specification. The specification only provides an Asp polypeptide comprising the amino acid sequence of SEQ ID NO: 1. Thus, it would require undue experimentation for one skilled in the art to practice the invention as claimed for the reasons stated above and in the previous office action.

Therefore, NO claim is allowed

All other rejections and/or objections are withdrawn in view of applicant's amendments and arguments there to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER